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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,763	01/27/2000	Eiko Masatsuji	Q54487	1343

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/09/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/492,763

Applicant(s)

MASATSUJI ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. acknowledgement is made of amendment filed November 30, 2001 and declaration under 37 USC 1.132 filed march 29, 2002.
2. Claims 7-8 and 10-15 are canceled.
3. Claims 16-20 are added.
4. Claims 1-6 and 9 are amended.

Election/Restrictions

5. Newly submitted claims 16-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

I. The claims 1-6 and 9 are directed to a dermal composition comprising a therapeutically effective amount of compound of formula (3) which liberates ascorbic acid in vivo.

II. Claim 16 is drawn to a method of preventing or treating acne comprising administering the composition of group I.

III. Claims 17 and 18 are drawn to a method of inhibiting the growth of Propionibacterium or staphylococcus comprising administering the composition of group I.

IV. Claim 19 is drawn to a method for inhibiting the activity of lipase derived from microorganisms comprising administering the composition of group I.

6. Since applicant has already received an action on the merits for the originally presented invention, it is proper that the group I has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-20 are

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withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Eventhough applicant is amended those newly submitted method claims to include the elected compound of formula (3), these claims are again subject to restriction requirement due to the reasons below.

7. Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

8. Inventions II and III (or IV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

9. For instance, US 5929109 teaches a method of inhibiting propionibacterium using various material including L-ascorbic acid but not limited to not only ascorbic acid-2-[hosphate zinc salt of formula (3) but also other fatty esters of L-ascorbic acid.).

Tretinoin is used in acne treatment and the combination of ascorbic acid and tretinoin is used in various treatments, not only acne but also other proliferative skin diseases (see US5,643,585). Furthermore, the irritation of tretinoin could be relieved by the method which uses materially different product such as zinc salt of retinoic acid (see US 4,214,000). A reference which anticipates each invention would not render any other invention obvious, absent ancillary art.

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10. Thus the newly submitted claims are properly withdrawn from the consideration and the restriction is proper and made it Final due to the reasons above and mentioned in previous office action.

Claim Objections

11. Claims 1-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claim 9 is drawn to a composition comprising the compound of formula (3). Claims 1-6 are further limiting the use of the composition of claim 9 rather than limiting the structural description.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 1-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al (US 5,516,919) in view of Fahim(US 4372296) or Schinitisky(US 4938969).

Claims read on to a dermal composition comprising a therapeutically effective amount of compound of formula (3) which liberates ascorbic acid in vivo.

Sano teaches salts of ascorbic acid-2-phosphate(e.g. magnesium or ammonium salts of ascorbic acid -2-phosphate) and its superior quality utilized in cosmetic and medicine field. It further teaches that various metal salts can be made by treating ascorbic acid-2-phosphate with a basic aqueous solution of ammonium, or zinc salts of

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organic acid(e.g. zinc carbonate), alkali metal(e.g. magnesium); see column 2, lines 29-34 and claim 9. Even though Sano teaches all the critical elements including the use of Zinc carbonate as a source of salt formation, Sano fails to exemplify the specific example of zinc salt of ascorbic acid -2- phosphate among other examples.

However it would have been obvious to one of ordinary skill in the art to formulate the zinc salt of ascorbic acid-2-phosphate for dermatologic use when it is modified in view of Schitinistky or Fahim(as mentioned in previous office action) because each patentee teaches the advantages of ascorbic acid when it is combined with zinc salt in topical cosmetic and medical composition.

One would have been motivated to make the zinc salt of ascorbic acid-2-phosphate because the advantages in Sano's reference will be enhanced by addition of zinc salt since zinc is essential in maintaining normal skin conditions and has extra beneficial effects as taught for instance in Schitinitsky; see column 2, lines 54-64. Thus one would have expected the success of the said modification without difficulty within the skilled level of the artisan due to the popularity and common utility of ascorbic acid in cosmetic and medical field , in addition to the skills and techniques already suggested in Sano's reference.

Response to Arguments

14. Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection. Because the claims has been amended, the previous 102 rejection is no longer valid.

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15. The declaration under 37 USC 1.132 is entered properly . However it is not been considered because the statement made by applicant is rather subjective not relative statement with the factual support for the proof of its superiority compared to other salts of ascorbic acid 2 phosphate(i.e. Applicant simply stated that zinc salt of ascorbic acid -2-phosphate is superior than any others; see experiment 2-7 in instant declaration-no data provided for showing factual support on its unexpected superiority). No weight should be given to an opinion affidavit. The results must be disclosed. Thus the deficiency has found in 1.132 declaration and the declaration is not considered to be effective.

Conclusion

16. All the claims 1-6 and 9 are maintained as rejected.

17. The claims 16-20 are withdrawn from the consideration.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

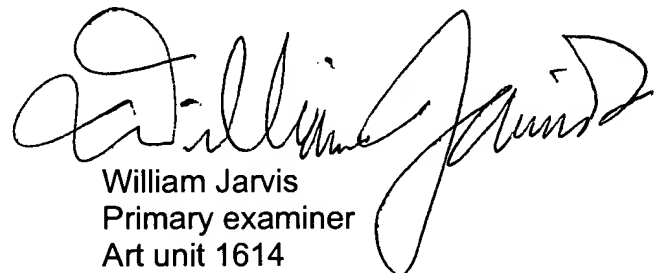
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
April 5, 2002



William Jarvis
Primary examiner
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